PATENT
Docket No. 473912000100

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Benjamin D. Pless

Serial No.: 09/629,242

Filing Date: July 31, 2000

For: PROCEDURES FOR PHOTODYNAMIC CARDIAC ABLATION THERAPY AND DEVICES FOR THOSE PROCEDURES

Examiner: H. Johnson

Group Art Unit: 3739

DECLARATION OF E. THOMAS WHEELOCK
PURSUANT TO 37 C.F.R § 1.131

Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

I, E. Thomas Wheelock, declare as follows:

1. I am a U.S. patent attorney (Reg. No. 28,825) at Morrison & Foerster LLP. At the direction of the inventor, Dr. Benjamin D. Pless, I personally drafted the above-referenced patent application during 2000, and am familiar with the contents of that application.

2. I understand that the claims of that patent application are currently being rejected as unpatentable over the disclosure in Publication No. US 2002/0095197A1 to Lardo et al. ("the Lardo application"), and the provisional patent application to which the Lardo patent claims priority, which provisional parent application was filed on July 11, 2000. This declaration shows

my belief, based on the attached written evidence, that the invention claimed in the U.S. Patent Application No. 09/629,242, ("Procedures for Photodynamic Cardiac Ablation Therapy and Devices for Those Procedures") was conceived by inventor Benjamin Pless prior to the July 11, 2000 priority date of the Lardo application, and thereafter diligently reduced to practice by filing on July 31, 2000.

3. I received a document from Dr. Pless prior to July 11, 2000 entitled "Epicor invention disclosure," a copy of which is provided as Exhibit A and discussed below, explaining a photodynamic cardiac ablation therapy method and device. Thereafter (also prior to July 11, 2000), I began drafting a utility patent application disclosing those methods and devices, which application was filed in the United States Patent and Trademark Office on July 31, 2000 (U.S. Patent Application No. 09/629,242, "Procedures for Photodynamic Cardiac Ablation Therapy and Devices for Those Procedures"). The following paragraphs summarize the documents attached to this declaration which are submitted as evidence of these statements. Each of the attached documents was prepared in the United States.

4. *Exhibit A* is a copy of a document entitled "Epicor invention disclosure." I received that document from Dr. Pless. Based upon my personal recollection of the document in Exhibit A and the date of the contents of the letter in Exhibit C, it is my belief that I received the document prior to July 11, 2000. In Exhibit A, the dates (each of which are prior to July 11, 2000) and the portions of the document that are not relevant to this declaration have been redacted or obscured. The text of Exhibit A provides a method for producing patterned lesions in cardiac tissue by subjecting cardiac tissue containing a photodynamic drug to a specific light source, where the light source is arranged to produce a lesion in a pattern corresponding to the light source. Paragraph 3 of the section entitled "Summary of the invention" states,

> "a patient is given the photodynamic drug prior to the ablation procedure. During the procedure, a catheter or other device containing a light source, or light guides (typically fiber optics) connected to a light source, is placed on the heart in the area that the physician wants to create a lesion. The heart is then illuminated with high intensity light, triggering the photodynamic reaction in the localized area where the lesion is desired."

Exhibit A further explains a device for providing light to cardiac tissue containing a photodynamic drug to create lesions on that cardiac tissue. Paragraph 4 (referring to Figure 2) of the section entitled "Detailed description" states, "Figure 2 shows a device to deliver light from a light source to the epicardium of the heart... At the distal end, the fiber optics terminate in an elongated window that allows light to escape. The back side of the window (18) is opaque to ensure that no light escapes to reach tissues other than those targeted by the physician," showing that Dr. Pless conceived of a light emitting device for photodynamic cardiac ablation in which a transparent region is used to transmit light to cardiac tissue to form a patterned lesion and methods for its use.

5. *Exhibit B* is a copy of a report outlining my law firm time notes. This time note report is generated from electronic records kept in the normal course of business, and was prepared at my request. In Exhibit B, each of the dates is prior to July 11, 2000. The dates and other portions of the document that are not relevant to this declaration have been obscured. Descriptions of the work done and the time taken for the noted work are typically revised for inclusion into a billing statement and sent to the client. Exhibit B indicates that I drafted and revised the patent application prior to July 11, 2000, and that I filed it on July 31, 2000.

6. *Exhibit C* is a copy of a letter from James W. Hellwege of the law firm of Jones, Tuller & Cooper, P.C. to me, responding to my request that he perform a patentability search on methods and devices for photodynamic cardiac ablation therapy. In Exhibit C, the dates (all of which are prior to July 11, 2000) and the portions of the document that are not relevant to this declaration have been obscured. It was my practice in patentability search requests to Mr. Hellwege to include a copy of a clients "invention disclosure" to provide Mr. Hellwege with a maximum breadth of information upon which to base a search. Exhibit C mentions that the search was to be directed to the method and devices for photodynamic cardiac ablation found in my "telefax letter." On page 1 of Mr. Hellwege's letter, paragraph 2 specifically states,

> "the search was directed to a device for creating a lesion in cardiac tissue. The lesion is created by administering a photodynamic drug to the desired region of the heart and applying light over a range of frequencies. The light source contains a LED or a lens connected to a series of fiber optic cables. These light sources

allow the lesion to be created without generating heat and thereby shields the non-target tissue."

Exhibit C shows a description of a procedure and device as later claimed in this application made prior to July 11, 2000.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to by true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

May 7, 2004

E. Thomas Wheelock (Reg. No. 28,825)